

**CLAIMS**

1. Method for selecting a particular population of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value equal or higher than 5.5, which value is calculated as the ratio between respectively the percentage of women having no pathologies, comprising the following steps in order:
- a) determination of the levels of sialidase by means of the procedure described in Cauci et al. Am J Obstet Gynecol 1998; 178; 511-5 and/or prolidase activity by means of the procedure described in Cauci et al. J Infect Dis 1998; 178; 1698-706 in samples of body fluid;
  - b) determination of the pH value of said body fluid samples;
  - c) selecting the samples having a sialidase value equal or above 5.0 nmol of methoxyphenol and/or a prolidase level equal or above 1500 mOD for prolidase and a pH  $\geq$  5.0.
2. Method as set forth in claim 1, in which the pH is  $\geq$  5.0 and  $\leq$  7.0, preferably  $\geq$  5.0 and  $\leq$  6.0, more preferably  $\geq$  5.0 and  $\leq$  5.5.
3. Method as set forth in claim 1, in which after the a) phase a score of said levels of sialidase and/or prolidase activity is determined.

4. Method as set forth in claim 1, in which said method is carried out in samples of vaginal fluid.

5. Method as set forth in claim 1, in which the obstetric or gynecologic pathologies comprise: low birth weight (LBW), very low birth weight (VLBW) preterm delivery (PTD), early preterm delivery (EPTD), premature rupture of membranes, preterm premature rupture of membranes, intraamniotic infections, spontaneous abortion, endometritis, obstetric surgery infections, post-partum or post-gynecologic surgery infections, pelvic surgery infections, upper genital tract infections which cause infertility, pelvic inflammatory disease (PID), annexitis, cervicitis, sexually transmitted diseases and infections, malignancies of the urogenital tract.

6. Method as set forth in claim 1, in which said population of women has the risk of said pathologies at a period of gestation less than 37 weeks, preferably less than 35 weeks, more preferably less than 32 weeks..

7. Method as set forth in claim 1, in which said method is carried out in samples of body fluid of pregnant women.

8. Method as set forth in claim 7, in which said method is carried out in samples of body fluid of women in the first or second trimester of gestation.

9. Method as set forth in claim 7, in which said method

is carried out in samples of body fluid of women from the sixth to the twenty-fourth full week of gestation.

10. Method as set forth in claim 1, in which said method is carried out in samples of body fluid of non-pregnant  
5 women.

11. Method as set forth in claim 1, in which said OR value is calculated and corrected by a standard factor by the SPSS computer statistic program.

12. Method for selecting a particular population of women  
10 having a risk of developing, VLBW, delivery at < 37 weeks' gestation, < 35 weeks' gestation or < 32 weeks' gestation, comprising the following steps in order:

a) determination of the levels of sialidase by means of the procedure described in Cauci et al. Am J Obstet  
15 Gynecol 1998; 178; 511-5 and/or prolidase activity by means of the procedure described in Cauci et al. J Infect Dis 1998; 178; 1698-706 in a sample of body fluid;

b) determination of the pH value of said body fluid sample;

20 c) selecting the samples having a  $\text{pH} \geq 5.0$  and a sialidase value above 0.19 nmol of methoxyphenol and/or a prolidase value above 22 mOD.

13. Method according to claim 12, wherein the step c) comprises selecting the samples having a  $\text{pH} \geq 5.0$ ,  
25 sialidase level of over 2.50 nmol of methoxyphenol or

prolidase level of over 1000 mOD.

14. Method according to claim 12, wherein the step c) comprises selecting the samples having a pH  $\geq$  5.0, a sialidase value above 0.19 nmol or 0.38 nmol or 2.5 nmol of methoxyphenol when it is selected a prolidase value of over 1000 mOD.

15. Method according to claim 12, wherein the step c) comprises selecting the samples having a pH  $\geq$  5.0, a sialidase value of 0.38 nmol of methoxyphenol and a prolidase value of over 22 mOD or over 44 mOD or over 1000 mOD or over 1500 mOD or over 2000 mOD.

16. Method according to claim 12, wherein said risk is indicated as OR value equal or higher than 5.5, which value is calculated preferably by the SPSS computer statistic program.

17. Kit for the determination of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value higher than 5.5, calculated preferably by the SPSS computer statistic program, comprising a sialidase and/or prolidase activity assay in solution that includes a colorless substrate solution in which to inoculate the biologic sample; a developing solution in a container equipped with dispenser; a reference scale to correlate the level of sialidase activity equal or above 0.19 nmol of methoxyphenol and/or the level of prolidase equal or

above 22 mOD with the intensity of the developed color; a pH indicator; a reference scale to correlate the pH detected by said indicator with a pH  $\geq$  5.0 and an illustrative leaflet containing the instructions for the proper use of the kit.

18. Kit according to claim 17, wherein said kit is used with a sample of body fluid of women.

19. Kit according to claim 17, wherein said body fluid is a vaginal fluid.

10 20. Kit according to claim 17, wherein said pH indicator comprises a revealing paper with a turning interval in the range between 5.0 and 7.0, preferably between 5.0 and 6.0, more preferably between 5.0 and 5.5.

21. Kit according to claim 17, wherein said reference scale for the sialidase and/or prolidase activity reports standard values associated with enzyme detecting colors.

22. Kit according to claim 21, wherein said reference scale for pH value associates said turning interval with a particular color intensity of the same color.

20 23. Kit according to claim 17, wherein said illustrative leaflet correlates the enzymatic activity with the pH value in order to evaluate the risk of pathologies as: absent or low (-), medium (+), high (++), very high (+++).

25 24. Kit according to claim 16, including a test on solid

support, preferably on reactive strip or platform test, for the determination of the sialidase and/or prolidase activity.

25. Kit according to claim 17, comprising as chromogenic  
 5 or fluorogenic substrate for the determination of sialidase activity a reagent chosen in the group comprising:  
 2-(3'-methoxyphenyl)-N-acetyl-D-neuraminic acid,  
 2-O-(o-nitrophenyl)-alpha-D-N-acetyl neuraminic acid,  
 2'-(4-methylumbelliferyl)-alpha-D-N-acetyl  
 10 neuraminic acid sodium salt, 5-bromo-4-chloro-3-indolyl-alpha-D-N-acetyl neuraminic acid.

26. Kit according to claim 25, comprising as chromogenic or fluorogenic substrate for the determination of prolidase activity a reagent chosen in the group  
 15 comprising: L-proline-para-nitroanilide, L-proline-beta-naphthylamide,  
 N-benzyloxycarbonyl-L-prolyl-beta-naphthylamide,  
 N-benzyloxycarbonyl-L-proline-para-nitrophenyl ester, hydroxy-L-prolyl-beta-naphthylamide,  
 L-proline-7-amido-4-methyl-coumarin, L-proline-4-methoxy-  
 20 beta-naphthylamide.

27. Kit for the determination of women having a risk of developing LBW, VLBW, PTD, delivery at < 37 weeks' gestation, < 35 weeks' gestation or < 32 weeks' gestation, comprising a sialidase and/or prolidase  
 25 activity assay in solution that includes a colorless

substrate solution in which to inoculate the biologic sample; a developing solution in a container equipped with dispenser; a reference scale to correlate the level of sialidase activity equal or above 0.19 nmol of  
5 methoxyphenol and/or the level of prolidase equal or above 22 mOD with the intensity of the developed color; a pH indicator; a reference scale to correlate the pH detected by said indicator with a pH  $\geq$  5.0 and an illustrative leaflet containing the instructions for the  
10 proper use of the kit.